

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
20 November 2003 (20.11.2003)

PCT

(10) International Publication Number
WO 2003/094886 A3

- (51) International Patent Classification⁷: **A61K 38/11**, 9/20 // 47/42 (74) Agent: **BATES, Philip, Ian**; Reddie & Grose, 16 Theobalds Road, London WC1X 8PL (GB).
- (21) International Application Number: PCT/IB2003/002368 (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (22) International Filing Date: 7 May 2003 (07.05.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0210397.6 7 May 2002 (07.05.2002) GB
PCT/IB02/04036
20 September 2002 (20.09.2002) IB
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- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- (88) Date of publication of the international search report: 22 July 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*



WO 2003/094886 A3

(54) Title: DESMOPRESSIN IN AN ORODISPERSIBLE DOSAGE FORM

(57) Abstract: Good bioavailability of desmopressin can be obtained by means of an orodispersible pharmaceutical dosage form which provides for a rapid dispersion of the active substance in the oral cavity. Thereby, desmopressin may be absorbed across the sublingual, buccal and/or gingival mucosa, and/or from the gastrointestinal tract for systemic distribution. Preferred dosage forms comprise desmopressin and an open matrix network which is an inert water-soluble or water-dispersible carrier material. Desmopressin formulated in this way is useful for voiding postponement, or the treatment or prevention of incontinence, primary nocturnal enuresis (PNE), nocturia or central diabetes insipidus. A process for the production of the dosage form by subliming solvent from a composition comprising desmopressin and a solution of carrier material is also provided.

INTERNATIONAL SEARCH REPORT

Inter. Application No

PC 1/1 B 03/02368

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K38/11 A61K9/20 //A61K47/42

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data, BIOSIS, MEDLINE, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 764 378 A (KEITH ALEC D ET AL) 16 August 1988 (1988-08-16) claim 31; examples 6-10 abstract	1-3, 11-17
Y	---	4-10
X	EP 0 517 211 A (TEIKOKU SEIYAKU KK) 9 December 1992 (1992-12-09) page 3, line 30 - line 36 page 4, line 21 - line 26; claim 8; examples 7,8 abstract	1-17
Y	---	4-10
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

6 November 2003

Date of mailing of the international search report

19.03.04

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 03/02368

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 59423 A (WATSON PHARMACEUTICALS INC) 12 October 2000 (2000-10-12) example 6 abstract	1-6, 11-17
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Y	WO 00 61117 A (GREEN RICHARD ;MURRAY OWEN (GB); HALL MICHAEL (GB); KEARNEY PATRIC) 19 October 2000 (2000-10-19) page 12, line 6 page 18, line 11 - line 14; claim 10; example 1 abstract	4-10
X	---	
X	US 5 849 322 A (GUTNIAK MARK K ET AL) 15 December 1998 (1998-12-15) example 10 abstract	1-6, 11-17
Y	---	4-10
X	US 5 298 256 A (FLOCKHART IAN R ET AL) 29 March 1994 (1994-03-29) column 3, line 27 - line 38 column 5, line 27 - line 40 abstract	1-6, 11-17
Y	---	4-10
X	ASHLEY GROSSMAN ET AL: "Two new nodes of desmopressin (DDAVP) administration" BRITISH MEDICAL JOURNAL, 17 May 1980 (1980-05-17), page 1215 XP002260408 Comment line 3 - line 5	1-6, 11-17
A	---	
A	WO 00 44351 A (SCHERER CORP R P) 3 August 2000 (2000-08-03) page 20, line 22 -page 21, line 8 abstract	1-17
A	---	
A	F. LACZI ET AL: "Effects of vasopressin analogues (DDAVP, DDAVP) in the form of sublingual tablets in central diabetes insipidus" INTERNATIONAL JOURNAL OF CLINICAL PHARMACOLOGY: THERAPY AND TOXICOLOGY, vol. 18, no. 12, 1980, pages 63-68, XP002260419 the whole document -----	1-17

INTERNATIONAL SEARCH REPORT

ational application No.
PCT/IB 03/02368

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 14-15
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-17

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-17

Claims: 1-17 directed to an orodispersible pharmaceutical dosage form of desmopressin, and a process for preparing the dosage form.

2. Claims: 18-27 (partly)

Claims 18-27 (partly) directed to an orodispersible pharmaceutical dosage form of somatostatin or an analogue thereof and a process for preparing the dosage form.

3. Claims: 18-27 (partly)

Claims 18-27 (partly) directed to an orodispersible pharmaceutical dosage form of an enkephalin and a process for preparing the dosage form.

4. Claims: 18-27 (partly)

Claims 18-27 (partly) directed to an orodispersible pharmaceutical dosage form of an oxytocin analogue and a process for preparing the dosage form.

5. Claims: 18-27 (partly)

Claims 18-27 (partly) directed to an orodispersible pharmaceutical dosage form of an LH-RH analogue and a process for preparing the dosage form.

6. Claims: 18-27 (partly)

Claims 18-27 (partly) directed to an orodispersible pharmaceutical dosage form of GnRH analogues and a process for preparing the dosage form.

7. Claims: 18-27 (partly)

Claims 18-27 (partly) directed to an orodispersible pharmaceutical dosage form of a vasopressin analogue and a

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

process for preparing the dosage form.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 14-15

Claims 14-15 relate to methods of treatment of the human or animal body by surgery or by therapy/diagnostic methods practised on the human or animal body/Rule 39.1.(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compounds/compositions.

INTERNATIONAL SEARCH REPORT

Application No

PCT/IB 03/02368

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